MAY 12 2014 K140606
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ScanMed®
The Image is Everything

Resonance Innovations, LLC
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www.scanmed.com

**Section 8. 510(k) Summary, K140606**

| | |
|---|---|
| **Submitter's Name:** | Resonance Innovations LLC |
| **Submitter's Address:** | 9840 South 140th St., Suite 8<br>Omaha, NE 68138 |
| **Submitter's Telephone:** | 402-934-2650 |
| **Submitter's Contact:** | Randall Jones, President |
| **Date 510(k) Summary prepared:** | April 21, 2014 |
| **Proprietary Name:** | PROCURE™ Array Coil Family |
| **Common or Usual Name:** | MRI coil(s) |
| **Classification Name:** | Coil, Magnetic Resonance, Specialty |
| **Classification Code:** | MOS |
| **Predicate Device:** | 1.5T ScanMed® PV Array, K022395 |

**Description of the Device**

The PROCURE™ Coil Family interfaces with a 1.5T or 3.0T 8-channel GE MRI scanner and provides high-quality images of the reproductive and urological anatomies in an easy-to-position, wearable, and very flexible design. This lightweight SemiFlex™ design facilitates effortless and accurate positioning similar to wearing a diaper and positions the multiple antenna elements as close as possible to the target anatomies regardless of patient size. The enclosure for the antenna set is made of flexible liquid impermeable, biocompatible materials, and the coil is accompanied by disposable liners (USP Class 6 PET) easily changed between patients, should scanning without clothing be desired. The two coils in the product family are identical in design, construction, materials, and operation, with the exception of resonant frequency. The designs and materials used for manufacture of both coils are identical to standard MRI coil technology that has existed for several years. The coils use similar blocking networks and impedance matching circuits, and they do not transmit energy into the patient, neither predicate nor current submission.

This phased array coil also accommodates popular biopsy systems, both delivered via an opening near the anus and/or vagina, neither included in the scope of this submission as they are independently operated and cleared by the FDA

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| Device Model Number | Device Description |
|---|---|
| 508GE1501 | 1.5T PROCURE Array Coil |
| 508GE3001 | 3.0T PROCURE Array Coil |

**Intended Use**

The intended use of this PROCURE Array coil family is to provide high-quality images of the reproductive and urological anatomies in an easy-to-position, wearable, and very flexible design.

**Indications for Use**

The coil is indicated for use by the order of a physician to be used as an accessory to a General Electric 1.5T or 3.0T magnetic resonance scanner for general human anatomy imaging as supported by the scanner. These images, when interpreted by a trained physician, may assist in medical diagnosis.

**Technological Characteristics**

The comparison between the predicate and the current submission is described, below.

1. **Design**. This submission is for a dedicated coil that may give diagnostic quality images of the reproductive and urological anatomies. It is a multi-channel coil with all channels designed to work at once, receive-only, in conjunction with the system Body Coil. The predicate multi-channel, PV Array covers very similar ranges of anatomy, also working as receive-only to the Body Coil. Both predicate and modified coils have semi-flexible anterior and posterior sections, with an antenna section between the legs. The modified device is more form-fitted to allow the antenna geometry to physically closer to the patient's anatomy. All design principles employed are mature and well-known throughout the industry.
2. **Principles of operation**: The scientific principles of operation (magnetic resonance) are identical between the predicate and modified devices. Theory of operation is very well understood throughout the industry.
3. **Materials**. The same materials are used in the construction of the predicate and modified devices. All internal circuitry is encapsulated in flame retardant EVA foam, then completely covered with a nylon fabric or compressed EVA. This nylon fabric has been successfully used for over 10 years in the predicate device with no reported biocompatibility issues. Both modified and predicate devices have been tested for mechanical and electrical safety using IEC60601-1 3rd Edition.
4. **Chemical Composition**. Both predicate and modified devices have a successful biocompatibility track record, as demonstrated by cytotoxicity testing and by their history of use in previously cleared devices.

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5. **Energy Source**. Both of these products are receive-only coils not generating their own power, but rather controlled by the MRI system as the energy source.

**Non-Clinical Tests**

The coils have similar dimension in the head area and have induced similar fields by the transmit coil (Body Coil) that stimulates them. The predicate and current submission have been subject to similar risk management studies, as listed below, and determined to be substantially equivalent.

1. Blocking Analysis
2. SNR and uniformity analysis
3. Risk management (including hazard analysis and FMEA)
4. Heat Testing
5. Compliance testing to IEC60601-1 3rd Edition

**Clinical Tests**

Analyses in all 3 planes (sagittal, coronal and transverse) were run on the PROCURE Array product to show that the anatomies of the submitted and predicate coils have substantial equivalence; the predicate device images the thorax, abdomen, pelvis and hip regions, and the current submission is designed for imaging the reproductive and urological anatomies.

**Substantial Equivalence Decision**

As described in this summary, the modified device is substantially equivalent to the predicate device based on the analysis herein. The modified device raises no new concerns of safety or efficacy. Note that the predicate device was made by Medic, Inc., which is a historic company name. Resonance Innovations is under the same leadership, and for both the dba is ScanMed®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 12, 2014

Resonance Innovations, LLC
% Mr. Randall Jones
President & CEO
9840 South 140th Street
OMAHA NE 68138-3693

Re: K140606
Trade/Device Name: 1.5T PROCURE™ Array Coil; 3.0T PROCURE™ Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 28, 2014
Received: April 22, 2014

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

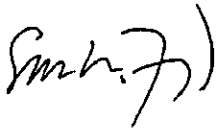
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140606

Device Name
PROCURE Array Family

Indications for Use *(Describe)*
The coil is indicated for use by the order of a physician to be used as an accessory to a General Electric 1.5T or 3.0T magnetic resonance scanner for general human anatomy imaging as supported by the scanner. These images, when interpreted by a trained physician, may assist in medical diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*